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EXAMINER

PATEL, MITAL B

ART UNIT PAPER NUMBER

3743

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/616,483

Applicant(s)HOFFMAN, ANDREW M. **Examiner**

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-14,22-35 and 43-45 is/are rejected.
- 7) ☒ Claim(s) 15-21 and 36-42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment/Arguments

1. The declaration filed on 7/22/04 under 37 CFR 1.131 is sufficient to overcome the Barney et al reference.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 4, 6, 7, 8, 10, 11, 12, 13, 14, 22, 25, 26, 27, 28, 29, 30, 32, 33, 34, 35 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Foley et al (US 5,042,467).
4. **As to claim 1**, Foley et al teaches a drug delivery device for a mammal comprising a cup-shaped body **30**, said body enclosing only one external nare (it **should be noted that the device of Foley et al is fully capable of enclosing only one external nare without extending into the nostril since applicant recites use for a mammal and the nares of mammals vary from species to species and amongst species as well**), wherein the device does not extend into the nostril of the mammal and the device comprises an interfacing lumen the diameter which does not enclose a second nare of the mammal (**See Figure 2**), and wherein said device comprises a unidirectional inhalation valve **46** and lacks an exhalation valve.

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5. **As to claim 3**, Foley et al teaches a device wherein the device does not enclose the mouth of the mammal **(it should be noted that the device of Foley et al is fully capable of enclosing only one external nare without extending into the nostril since applicant recites use for a mammal and the nares of mammals vary from species to species and amongst species as well)**.

6. **As to claim 4**, Foley et al teaches a device wherein the device comprises a patient-actuated inhalation valve **(See Col. 3, lines 65-67)**.

7. **As to claim 6**, Foley et al teaches a device wherein the interfacing lumen comprises a diameter which covers only one nare and not both nares a horse, a cow, a sheep, or a goat **(it should be noted that the device of Foley et al is fully capable of enclosing only one external nare without extending into the nostril of any of the above listed species/mammal)**.

8. **As to claim 7**, Foley et al teaches a device wherein the device is adapted for use on a horse **(it should be noted that the device of Foley et al is fully capable of enclosing only one external nare without extending into the nostril of any of the above listed species/mammal)**.

9. **As to claim 8**, Foley et al teaches a device wherein the cup-shaped body comprises a flexible interface for contacting the face of the mammal **(it should be noted element 30 is made from a plastic resin which material would exhibit flexibility)**.

10. **As to claim 10**, Foley et al teaches a device wherein the interface is straight **(See Fig. 2)**.

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11. **As to claim 11**, Foley et al teaches a device wherein the device comprises a spacer holding chamber **16**, the chamber being in communication with the cup-shaped body (**See Figure 4A**).

12. **As to claim 12**, Foley et al teaches a device wherein the chamber comprises a lumen **18** for receiving a therapeutic agent.

13. **As to claim 13**, Foley et al teaches a device wherein the lumen is adapted to receive an aerosol container **10**.

14. **As to claim 14**, Foley et al teaches a device wherein the lumen is adapted to receive a metered-dose inhaler (MDI) canister **10**.

15. **As to claim 22**, Foley et al teaches a device wherein the device lacks a rebreathing chamber (**See Fig. 3**).

16. **As to claim 25**, Foley et al teaches a drug delivery device for a mammal comprising a cup-shaped body **30**, said body enclosing only one external nare (it **should be noted that the device of Foley et al is fully capable of enclosing only one external nare without extending into the nostril since applicant recites use for a mammal and the nares of mammals vary from species to species and amongst species as well**), wherein the device does not extend into the nostril of the mammal and the device comprises an interfacing lumen the diameter which does not enclose a second nare of the mammal (**See Figure 2**); comprising a holding chamber **16** for holding the drug in a cloud suspension, said holding chamber being in communication with said cup-shaped body and comprising a unidirectional inhalation valve **46** and lacks an exhalation valve.

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17. **As to claim 26**, Foley et al teaches a device wherein the device does not enclose the mouth of said mammal (**it should be noted that the device of Foley et al is fully capable of enclosing only one external nare without extending into the nostril since applicant recites use for a mammal and the nares of mammals vary from species to species and amongst species as well**).

18. **As to claim 27**, Foley et al teaches a device wherein the device comprises a patient-actuated inhalation valve (**See Col. 3, lines 65-67**).

19. **As to claim 28**, Foley et al teaches a device wherein the interfacing lumen comprises a diameter which covers only one nare and not both nares a horse, a cow, a sheep, or a goat (**it should be noted that the device of Foley et al is fully capable of enclosing only one external nare without extending into the nostril of any of the above listed species/mammal**).

20. **As to claim 29**, Foley et al teaches a device wherein the device is adapted for use on a horse (**it should be noted that the device of Foley et al is fully capable of enclosing only one external nare without extending into the nostril of any of the above listed species/mammal**).

21. **As to claim 30**, Foley et al teaches a device wherein the cup-shaped body comprises a flexible interface for contacting the face of the mammal (**it should be noted element 30 is made from a plastic resin which material would exhibit flexibility**).

22. **As to claim 32**, Foley et al teaches a device wherein the interface is straight (**See Fig. 2**).

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23. **As to claim 33**, Foley et al teaches a device wherein the chamber comprises a lumen **18** for receiving a therapeutic agent.

24. **As to claim 34**, Foley et al teaches a device wherein the lumen is adapted to receive an aerosol container **10**.

25. **As to claim 35**, Foley et al teaches a device wherein the lumen is adapted to receive a metered-dose inhaler (MDI) canister **10**.

26. **As to claim 43**, Foley et al teaches a device wherein the device lacks a rebreathing chamber (**See Fig. 3**).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. Claims 9, 23, 24, 31, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al (US 5,042,467).

29. **As to claims 9 and 31**, Foley et al teaches essentially all of the limitations except for wherein the interface is angled. However, Applicant on page 5 discloses that the angling of the interface is optional. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that any interface would work equally as well.

30. **As to claims 23 and 44**, Foley et al teaches essentially all of the limitations except for wherein the interior volume of the device is approximately 200-500 milliliters. However, the volume of the device will depend on the intended therapy, i.e., how much medicament is to be given to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Foley et al to arrive at the claimed limitation depending on the intended therapy with respect to how much medicament is to be delivered to the user.

31. **As to claims 24 and 45**, Foley et al teaches essentially all of the limitations except for the length of the device. Applicant additionally states on page 1 of the specification that the length of the device may be scaled up or down to accommodate the features of the mammal. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Foley et al to arrive at the claimed limitation depending on the user as admitted by Applicant.

Allowable Subject Matter

32. Claims 15-21 and 36-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

33. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor render obvious the overall claimed combination of a method for preventing or treating a respiratory condition of a mammal using the device set forth in claims 1 and 25 wherein the device encloses only one

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external nare and does not extend into the nostril of the mammal and having an interface lumen the diameter of which does not enclose a second external nare of a mammal.

34. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5855202 and US 4470412.

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mital B. Patel
Examiner
Art Unit 3743

mbp

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